

## **Quality Management Plan**

### **DHI Maritime Technology Evaluation Facility, Denmark**

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## 1 ABBREVIATIONS AND TERMS

Abbreviation/Term	Definition	Comment
Active substance	A substance which has a general or specific action on aquatic organisms or bacteria (pathogens)	
Ballast Water Management System (BWMS)	A system which removes, renders harmless or avoids uptake or discharge of aquatic organisms and bacteria (pathogens) with ballast water and sediments by mechanical, physical, chemical or biological means acting individually or in combination	
Certification Body	Body to certify facilities to conduct land based test of BWMS according to the IMO Convention	Lloyds Registry is appointed as Certification Body in Denmark
Client	The party requesting a BWMS performance test.	
Convention	The IMO convention on ballast water (1)	
International Maritime Organization (IMO)	United Nations specialised agency with responsibility for the safety and security of shipping and the prevention of marine pollution by ships	IMO has adopted the International Convention for the Control and Management of Ship's Ballast Water and Sediments (1)
Procedure	Detailed description of the use of a standard or a method	The procedure specifies the implementation of a standard or a method in terms of, e.g., "equipment used"
Quality Assurance Project Plan (QAPP)	Project specific technical document describing the BWMS to be tested, the test facility, and other conditions affecting the actual design and implementation of the required experiments	
Quality Management Plan (QMP)	Document describing the quality control management structure and policies of the testing body (including subcontractors and outside laboratories)	
Standard Operation Procedure (SOP)	Generic document providing rules, guidelines or characteristics for tests or analyses	In-house methods may be used in the absence of a recognised standard, if they are commonly accepted for testing of BWMS or scientifically documented. In-house methods shall include measures for internal quality control

## **2 INTRODUCTION**

The introduction of invasive marine species into new environments by ballast water has been identified as a threat to aquatic ecosystems worldwide. The problem of invasive species is largely due to the expanded trade and traffic volume over the last few decades.

It is estimated that about 3-10 billion tonnes of ballast water are transferred globally each year, potentially transferring from one location to another species of live aquatic organisms that may prove ecologically harmful when released into a non-native environment.

The International Maritime Organization (IMO) has adopted the International Convention for the Control and Management of Ship's Ballast Water and Sediments (1) to reduce the risk of spreading of harmful aquatic organisms and pathogens released with ballast water.

The Convention requires that all ships comply with specified water quality requirements (D2) before ballast water is released into the environment.

DHI has established the DHI Maritime Technology Evaluation Facility (also referred to as the "test facility") in Hundested, Denmark, with the purpose to perform land-based tests of maritime technologies and particularly to verify that Ballast Water Management Systems (BWMS) perform in accordance with the D2 requirements of the Convention.

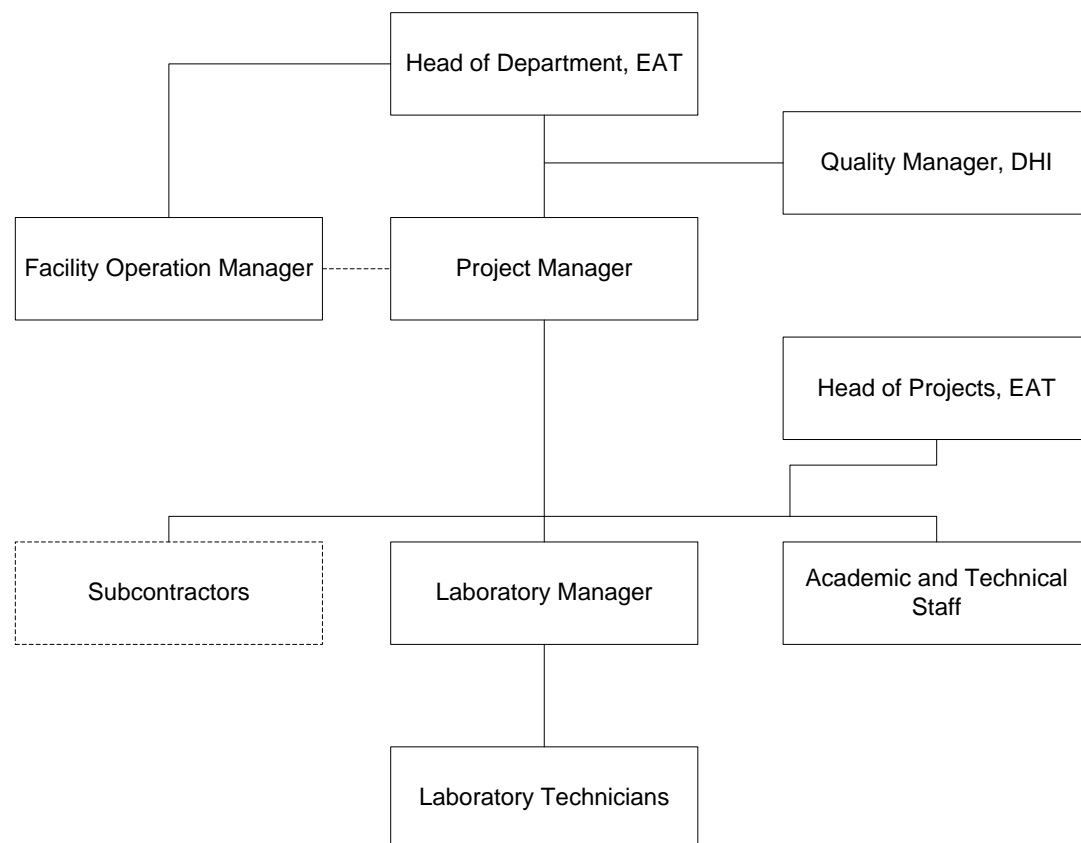
The aim of the evaluation conducted at the test facility is to provide independent, third party documentation for the performance of maritime technologies. The third party documentation shall be of the required quality in accordance with the international agreements. High quality is ensured through extensive quality management and use of skilled staff. The quality will be documented by manuals, procedures and quality requirements.

The performance evaluation of BWMS aims at documenting compliance with the requirements stated in the following references:

- Guideline for approval of ballast water management systems - G8 (2)
- Procedure for approval of ballast water management systems that make use of active substances - G9 (3).

### 3 ORGANISATION

The services connected to the DHI Maritime Technology Evaluation Facility are provided under the organisation shown in Figure 1.



*Figure 1. Organisation diagram for services conducted at the DHI Maritime Technology Evaluation Facility.*

#### **Quality Manager**

The DHI Quality Manager is responsible for assigning a trained internal auditor from DHI's Quality Assurance Unit to each project in accordance with the procedures for internal audit of the DHI Quality Management System.

The internal auditor is identified in the Quality Assurance Project Plan (QAPP). The internal auditor shall receive the QAPP from the Project Manager in order to plan and execute internal audit of the project.

#### **Head of Department**

The Head of Department, business strategy, for DHI's Department of Environment and Toxicology has the overall responsibility for the test facility. This includes the following tasks:

- Negotiation of contracts with clients
- Responsibility for overall co-ordination, planning and costs as required to ensure that the appropriate human resources, facilities and equipment are available for the services

- Appointment of the Project Manager
- Appointment of the Facility Operation Manager
- Business management of services conducted at the test facility, including e.g. co-ordination of services conducted with parallel or overlapping time schedules, via dialogue with the Project Manager and the Facility Operation Manager
- Approval of QAPP and Standard Operation Procedures (SOPs)
- Documentation according to the DHI Quality Manual which includes (i) maintenance of this QMP, (ii) records of staff training and experience, (iii) records of facilities and their maintenance, and (iv) records of complaints.

### **Project Manager**

The Project Manager is responsible for the management and efficient performance of the project in accordance with the contract between the client and DHI, the QMP, the QAPP, and the DHI Quality Manual.

The Project Manager's tasks include:

- Organisation and management of the project
- Periodic meetings and other communication with the client to ensure that all necessary information is available in due time
- Drafting of a QAPP with detailed description of the project including time schedule and quality assurance of deliverables
- Facilitation of the process for comments and responses to the draft QAPP in dialogue with the client and the Certification Body
- Responsibility for preparing the final QAPP, which shall be accepted by the client, and for approval of possible amendments and deviations to the QAPP
- Co-ordination and dialogue with the Facility Operation Manager in relation to safe conditions of work, logistics and technical operations at the test facility
- Co-ordination and dialogue with the Laboratory Manager in relation to the practical organisation of work involving laboratory technicians; the Project Manager shall in due time inform the Laboratory Manager on the types of tests and the required capacity to enable laboratory capacity planning
- Agreements with subcontractors as appropriate for meeting the project deliverables (e.g. chemical analytical laboratory)
- Communication of the project time schedule to the Certification Body to enable external audit
- Communication of the QAPP and project time schedule to the internal auditor identified in the QAPP to enable internal audit
- Approval of initiation of the test and interruption of test cycles, e.g. in case of irregularity.

**Facility Operation Manager**

The Facility Operation Manager is responsible for maintenance of the test facility as appropriate to fulfil the scope and the requirements described in the QMP and the QAPP.

The Facility Operation Manager is responsible for operating the test facility and for correct connection between the test facility and the technology which is the target for the testing.

**Head of Projects**

The academic and technical staff is appointed by the Head of Projects via dialogue with the Project Manager.

**Laboratory Manager**

The laboratory technicians are appointed by the Laboratory Manager via dialogue with the Project Manager.

**Academic and technical staff**

The academic staff (biologists, chemists and engineers), secretaries and the technical staff (excluding laboratory technicians) perform specific tasks allocated to them by the Project Manager. The tasks include:

- Contributions to the QAPP and SOPs
- Sampling at the test facility
- Monitoring of test water quality (e.g. biology; ecotoxicity; chemistry) to ensure that it complies with the IMO requirements
- Analyses and data treatment
- Contributions to the test report

**Laboratory technicians**

The laboratory technicians are responsible for performance of specific tasks allocated to them by the Project Manager. The tasks include:

- Contributions to the QAPP and SOPs
- Sampling at the test facility
- Maintenance of equipment
- Analyses and data treatment
- Contributions to the test report

## Global Ballast Water Management Team

A Global Ballast Water Management Team – organised with two members from the management in DHI Denmark and two members from the management in DHI Singapore – has the task to co-ordinate the development and marketing of services related to the Ballast Water within the DHI Group.

## 4 PERFORMANCE OF PROJECT

The flow of work for testing the performance of BWMS is depicted in Figure 2 in and described below.

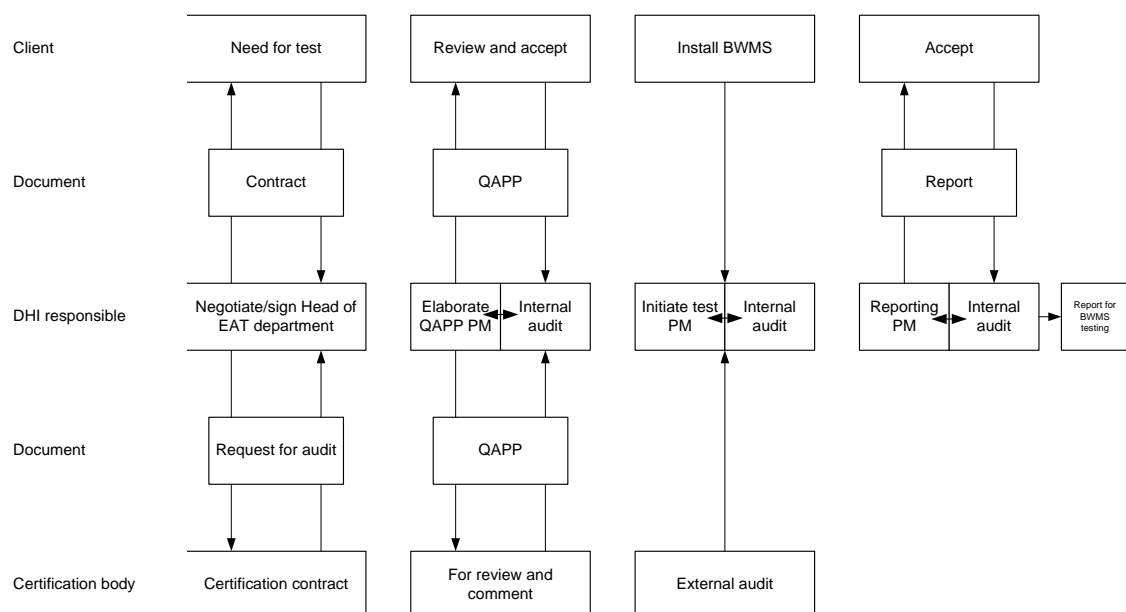


Figure 2. Flow of work in BWMS performance tests

### 4.1 Contract

A contract between the client and DHI is negotiated and signed according to the DHI manual for project management.

The contract normally contains a description of the scope of services, the personnel and quality assurance, the obligations of the client, and the time schedule and price.

### 4.2 Quality Assurance Project Plan

The QAPP is a project specific document describing the technology to be tested, the test facility, and other conditions affecting the actual design and implementation of the required experiments.

The QAPP is

- Prepared by the Project Manager

- Signed by the Project Manager, the Head of Department and the internal auditor from the DHI Quality Assurance Unit
- Forwarded (in one copy) to the Certification Body for review and comments
- Forwarded (in two copies) to the client for review, acceptance and signature.

The QAPP typically includes the following titles:

1. Study objective
2. Client
3. Client's monitor (if any)
4. Test facility
5. Subcontractors (if any)
6. Personnel responsible for the study
7. Description of the technology
8. Safe handling of active substances (if any)
9. Description of the test facility
10. Operational procedures (including procedures for operating the technology)
11. Testing procedures (e.g. procedures for obtaining the required test water qualities, ballasting, storage, in-tank treatment, de-ballasting and sampling)
12. Analyses (including chemical, biological and ecotoxicological analyses as appropriate)
13. Data processing
14. Validity criteria
15. Success criteria
16. Time schedule
17. Quality assurance and quality control
18. Reporting
19. Archiving

## 20. Deviations and amendments

The QAPP refers to a number of SOPs (see Appendix 1).

Amendments and deviations to the QAPP are approved and signed by the Project Manager. Amendments describe planned changes, whereas deviations describe unplanned changes to the QAPP.

The QAPP is subject to internal audit in accordance with the procedures for internal audit of the DHI Quality Management System.

### 4.3 Services

The project will be conducted as described in the QAPP and subsequent amendments and deviations. Testing can be initiated when the technology is installed and ready for operation. Initiation of testing is decided by the Project Manager after consulting with the client.

The Project Manager decides when a test cycle is completed and valid by reference to the requirements in G8 /2/ or G9 /3/. If required, the Project Manager can decide to interrupt a test cycle due to technical malfunctioning of the test facility, insufficient status of biological or physical parameters, or other reasons related to the quality of the test water.

The validity of the test is confirmed by the signature of the Project Manager, when all test cycles have been completed and confirmed valid.

### 4.4 Report

The report is typically structured by use of the appropriate headings in the QAPP and shall include a summary of any amendments and deviations to the QAPP.

The report shall include all relevant technical and analytical data and will contain at least the following:

- Names and addresses of the client and monitor
- Name and address of the testing facility and the dates, on which the test was initiated and completed
- Objectives and procedures stated in the approved QAPP including any changes made to the QAPP
- Results obtained, presented in summarizing tables and as raw data
- Any unforeseen circumstances which may have affected the quality or integrity of the land-based testing
- Storage locations of all raw data, the signed QAPP and report
- Descriptions of operations, calculations and transformations performed on the presented data
- Quality assurance statement.

The report shall be signed by the Project Manager, the internal auditor from the DHI Quality Assurance Unit, and the Head of Department.

Three copies of the final report will be prepared in English and forwarded to the client.

## **5 QUALITY MANAGEMENT PROCESSES**

Projects making use of the test facility are conducted in accordance with the principles of ISO 9001 /19/ by using the DHI Quality Manual and the procedures in this QMP. The Quality Management System of DHI is found compliant with ISO 9001 as part of the ISO 17025 accreditation of the DHI environmental laboratory. The DHI environmental laboratory is ISO 17025 accredited and authorised to carry out studies in compliance with the OECD Principles for Good Laboratory Practice (GLP).

### **5.1 Document and record control**

The DHI Quality Manual includes a procedure describing the process of drafting, revising and approving documentation. Standard operation procedures are controlled as described in SOP 30/944.

Procedure 8 in the DHI Laboratory Services Manual on laboratory data describes how records of the test are stored, transferred, maintained and controlled in order to ensure data integrity for a period defined in the QAPP, but not shorter than 5 years from completion of the verification.

### **5.2 Internal audits**

Procedure 3 in the DHI Quality System Manual on audit and evaluation and the Standard Operating Procedures for GLP (SOP 30/943 of the GLP documentation) describe the process of periodic internal auditing of projects and activities including audit responsibilities and planning, auditor training and competences and audit reporting.

Procedure 4 in DHI Quality System Manual on non-conformities and corrective actions describes how deviations identified during operation and auditing are corrected (corrective actions) and how future occurrence of the same deviations is prevented by improving the quality manual including the process descriptions and working methods (preventive actions).

### **5.3 Complaint management**

Procedure 5 in the DHI Project Management Manual on Complaints describes how complaints are recorded, resolved and reported. If not resolved, complaints are referred to the Certification Body for resolving.

### **5.4 Subcontractor management**

Procedure 4 in the DHI Project Management Manual on subcontractors describes how it is ensured that subcontractors follow quality requirements.

In addition, analytical laboratories providing analyses of any kind should:

- Maintain an ISO 17025 accreditation with the quality management system required herein.
- Apply accredited analytical methods when available.
- Apply other methods according to either international standard methods or in-house methods that are in all cases validated as required for accredited methods.

SOP 30/700 (Draft) furthermore describes how it is ensured that purchased items such as chemicals and glassware are controlled, accepted and calibrated.

## **5.5 Staff competence management**

Procedure 3 on appraisal interview, post qualifying education and experience in the DHI Employee Conditions Handbook describes how it is ensured that the projects are conducted by staff with adequate competences and knowledge. This is done by maintaining a list of functions in the test process with competence requirements and responsibilities. The list is supported by reference to staff files in the DHI CV-data base.

## **5.6 Facility management**

Procedure 1 in the DHI Laboratory Services Handbook on laboratory facilities describes how it is ensured that facilities and equipment are available and fit for the purposes.

## **5.7 Management review**

Procedure 3 of the Quality System Manual on audit and evaluation describes how the DHI management is ensuring that the test centre is working according to this quality manual through mechanisms such as e.g. an annual management review process.

The Quality Manager is responsible for maintenance and development of the quality system and for the internal auditing of all aspects of the system – with daily reference to the Director, Group R&D and Quality Management. The DHI Quality Manual contains rules for reviews of the quality system.

# **6 REFERENCES**

1. Anonymous. International Convention for the Control and Management of Ships Ballast Water and Sediments. London : International Maritime Organization, 2005.
2. MEPC. Guidelines for approval of ballast water management systems (G8). resolution MEPC.174(58). Adopted 10<sup>th</sup> October 2008.
3. MEPC. Procedure for approval of ballast water management systems that make use of active substances (G9). MEPC.126(53) Adopted 22<sup>nd</sup> July 2005.

## ***A P P E N D I X   1***

### ***Standard Operation Procedures***

SUBJECT/SUBSUBJECT	NO.
ANALYTICAL METHOD ZOOPLANKTON ANALYSIS	30/1700:02
ANALYTICAL METHOD MICROSCOPIC DETERMINATION OF MICROALGAE AND MICRO-ZOOPLANKTON	30/1701:01
ANALYTICAL METHOD DETERMINING PRIMARY PRODUCTION OF MICROALGAE	30/1702:01
ANALYTICAL METHOD DETERMINING DIVERSITY OF MICROALGAL COMMUNITIES BY HPLC ANALYSIS OF PIGMENTS	30/1703:01
ANALYTICAL METHOD DETERMINATION OF VIABLE ALGAE BY MPN	30/1704:01
MICROBIOLOGICAL TESTS DETERMINATION OF TOTAL NUMBER OF BACTERIA BY EPIFLUORESCENCE MICROSCOPY	30/1705:01
MICROBIOLOGICAL TESTS DETERMINATION OF HETEROTROPHIC PLATE COUNT	30/1706:01
MICROBIOLOGICAL TESTS DETERMINATION OF <i>VIBRIO CHOLERAE</i> IN WATER	30/1707:01
MICROBIOLOGICAL TESTS DETERMINATION OF TOTAL COLIFORM, <i>E. COLI</i> AND ENTEROCOCCI Colilert*-18 AND Enterolert-E	30/1708:01
MEASUREMENT METHOD OZONE MEASUREMENT IN WATER	30/1730:01
MEASUREMENT METHOD OZONE MEASUREMENT IN AIR	30/1731:01
MEASUREMENT METHOD TRO MEASUREMENT IN WATER	30/1732:01
HARVESTING, CULTIVATION AND ADDITION OF ORGANISMS	30/1734:02
COLLECTION OF SEAWATER	30/1735:01
COLLECTION OF FRESH WATER	30/1736:01
CHEMICAL CRITERIA FOR TEST WATER ADDITION OF DOC, POC AND MM	30/1737:01
SAMPLING BIOLOGICAL PARAMETERS	30/1738:01
SAMPLING WET TEST	30/1739:01
SAMPLING DBP ANALYSIS	30/1740:01
STATISTICS STATISTICAL SURVEILLANCE OF BIOLOGICAL DATA OBTAINED AT TESTS OF BWMSs	30/1760:01
LABELLING SAMPLES COLLECTED AT TEST SITE	30/1761:01
OPERATION OF THE DHI MTEF	30/1762:01
CLEANING RETENTION TANKS, PIPINGS AND OTHER EQUIPMENT AT TEST SITE	30/1763:01
MEASUREMENT METHOD ON-LINE MONITORING OF PRESSURE, TEMPERATURE AND FLOW RATES AT TEST SITE	30/1764:01
MEASUREMENT METHOD FLUORESCENCE	30/1765:01

SUBJECT/SUBSUBJECT	NO.
MEASUREMENT METHOD TURBIDITY	30/1766:01
HEALTH AND SAFETY ENSURING WORKER HEALTH AND SAFETY AT TEST SITE	30/1767:01
MEASUREMENT METHOD DETERMINATION OF TSS	30/1768:01
MEASUREMENT METHOD DETERMINATION OF DOC AND POC	30/1769:01

## ***A P P E N D I X   2***

### ***Survey of Lists***

### **Survey of Lists**

The lists mentioned below are kept together with the rest of quality documentation.

### **Certification Body**

DHI holds a statement describing the Certification Body which has certified the DHI Maritime Technology Verification Facility.

### **List of sub-contractors**

DHI keeps a list of sub-contractors used during the test. The list contains information about name of company, address, contact person, e-mail, telephone number and deliveries.

### **List of staff approved for functions at the test facility**

DHI keeps a list of persons working at the test facility. The list contains information about the person's activities, responsibility and documentation for training. The person's competence is documented in an available CV.

### **List of Standard Operation Procedures**

DHI keeps a list of Standard Operation Procedures including those used in relation to projects conducted at the test facility.

## ***A P P E N D I X   3***

### ***Template for Amendments to QAPP***

## **AMENDMENT**

QAPP DOCUMENT TITLE AND DATE:

AMENDMENT NUMBER:

DATE OF AMENDMENT:

AMENDMENT CONTENTS:

REASON FOR AMENDMENT:

IMPACT OF AMMENDMENT:

PREVENTATIVE ACTION:

If relevant, action to prevent that the same cause of amendment will reoccur in the future.

ORIGINATED BY:

SIGNED BY:

\_\_\_\_\_

Project manager

\_\_\_\_\_

DATE

APPROVED BY:

\_\_\_\_\_

Internal auditor

\_\_\_\_\_

DATE

Copy to be sent to the client and the Certification Body.

## ***A P P E N D I X 4***

### ***Template for Deviations from QAPP***

## **DEVIATION**

QAPP DOCUMENT TITLE AND DATE:

DEVIATION NUMBER:

DATE OF DEVIATION:

DESCRIPTION OF DEVIATION:

REASON FOR DEVIATION:

IMPACT OF DEVIATION:

CORRECTIVE ACTION:

If required, actions to be taken to prevent consequences of deviation

ORIGINATED BY:

\_\_\_\_\_

SIGNED BY

Project manager

\_\_\_\_\_

DATE

APPROVED BY:

\_\_\_\_\_

Quality manager

\_\_\_\_\_

DATE

Copy to be sent to the client, and the Certification Body.